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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,407	05/30/2001	Douglas J. LaCount	875.030US1	7075

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

### Application No.

09/870,407

### Applicant(s)

LACOUNT ET AL.

### Examiner

Gerald G Leffers Jr., PhD

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 30-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-17 is/are rejected.
- 7) ☒ Claim(s) 15, 18 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of an amendment, filed 1/20/2004, in which several claims were amended (claims 1-2, 5-11, 18, 23 & 26-29). Claims 1-68 are pending, with claims 30-68 withdrawn from consideration as being directed to nonelected inventions.

Any rejection of record not addressed herein is withdrawn. This action is FINAL.

### ***Drawings***

Receipt is acknowledged of a petition to accept color drawings, filed 1/20/2004. The examiner is in the process of obtaining the color drawings from the file repository and will be able to obtain a decision on applicants' petition at that time.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5-7, 11-14 and 16-17, 19, 23-29 rejected under 35 U.S.C. 102(e) as being anticipated by Plaetinck et al (US 2003/0061626 A1; see the entire application). **This rejection is maintained for reasons of record in the office action mailed 7/15/2003 and repeated below. The grounds of rejection are extended to claims 7 & 11 in response to applicants' amendment.**

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Plaetinck et al teach screening methods for determining the function of a gene utilizing expression vectors capable of expressing dsRNAs (e.g. Abstract). The DNAs expressed as dsRNA are obtained from cDNA or genomic libraries and can be known or unknown (e.g. Abstract; page 1 paragraph 0004). Expressions used in the methods taught by Plaetinck et al can have promoters arranged head to head where the promoter is of the same type (e.g. Figure 8, two T7 promoters) or of different type (e.g. Figure 15, T7/T3/Sp6 promoters). Plant cells and *C. elegans* cells are two types of cells that can be used in the methods taught by Plaetinck et al (e.g. page 2, paragraph 0015). The vector can be a vector for integration into the host cell genome (e.g. Figure 8, "RNAi integration vector").

### ***Response to Arguments***

Applicant's arguments filed in the response of 1/20/2004 have been fully considered but they are not persuasive. The response essentially argues that the amendment of the claims to include the limitation that the designated DNA sequence of interest "comprises" a DNA sequence from a protist distinguishes the claimed invention from the Plaetinck et al reference. This argument is not persuasive because the limitation "a double-stranded designated DNA sequence of interest comprising a DNA sequence from a protist" is open language and can be reasonably interpreted to simply mean that the designated sequence of interest comprises any sequence obtainable from a protist, including any dinucleotide sequence found in any protist. One would reasonably expect that such sequences would necessarily be present in the plant and *C. elegans* sequences taught by Plaetinck et al. Therefore, applicants' argument is not persuasive. It would be remedial with regard to the instant grounds of rejection to clearly indicate that the entire DNA sequence of interest is obtained from a protist.

Amended claim now recites “the designated DNA sequence comprises an essential gene, or gene fragment thereof, from a protist”. Again, the open language and the term “fragment thereof” encompasses any dinucleotide sequence that is obtainable from any essential protist gene sequence. This analysis applies as well to amended claim 11.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4, 8-10, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plaetinck et al (US 2003/0061626 A1; see the entire document) in view of Ngo et al (applicants' submission as part of the IDS submitted with the application papers; PNAS USA, Vol. 95, pages 14687-14692, December 1998; see the entire reference). **This rejection is maintained for reasons of record in the office action mailed 7/15/2003 and repeated below.**

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The teachings of Plaetinck et al are described above and are applied as before, except: Plaetinck et al do not teach the use of their system in protozoan cells to target essential genes.

Ngo et al teach the discovery that dsRNA induces mRNA degradation in *Trypanosoma brucei* (Abstract). The Ngo et al reference teaches that expression of the essential gene for  $\alpha$ -tubulin results in the formation of multinucleate cells and a specific block of cytokinesis followed by cell death (e.g. Abstract). Ngo et al specifically teach that the effect they've characterized is not limited to  $\alpha$ -tubulin mRNA but is applicable to other cellular RNAs and can be a powerful tool for genetically manipulating trypanosomes (e.g. Abstract). Ngo et al teach expression vectors that are dependent upon a head to head arrangement of repeat sequences (e.g. Figure 1). Ngo et al teach it is desirable to construct expression vectors that allow inducible expression of the dsRNAs (e.g. page 1496, column 1, last paragraph).

It would have been obvious to one of ordinary skill in the art at the time of applicants' invention to modify the techniques taught by Plaetinck et al for use in *Trypanosoma* as taught by Ngo et al because Plaetinck et al teach it is within the skill of the art to characterize the phenotype of a known or unknown gene in a host cell using expression vectors that express dsRNA and because Ngo et al teach that expression of dsRNA in *T. brucei* can result in the silencing of essential genes and that it is desirable to utilize dsRNA expression to characterize and genetically manipulate genes in *T. brucei*, an important human parasite. One would have been motivated to do so in order to receive the expected benefit of being able to inducibly express dsRNAs targeted to different genes in *T. brucei* in an inducible fashion in order to characterize their gene function. Absent evidence to the contrary, there would have been a

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reasonable expectation of success in using the constructs and methods taught by Plaetinck et al to characterize genes in *T. brucei* as taught by Ngo et al.

### ***Response to Arguments***

Applicant's arguments filed in the response of 1/20/2004 have been fully considered but they are not persuasive. The response essentially argues: 1) there was no motivation to combine the cited references, 2) mere conclusory statements are not sufficient to indicate a sufficient motivation to combine the references, and 3) the references themselves must provide the motivation to combine.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Plaetinck et al teach an efficient system for characterization of gene function in different organisms where the target sequence can be known or unknown. In the particulars of their system, Plaetinck et al teach the claimed invention with the exception of applying the invention to protists such as *Trypanosoma*. Ngo et al teach that it is desirable to utilize dsRNAs to manipulate protozoan microorganisms such as *Trypanosomes*. The motivation to combine the two references comes from the references themselves in that they are analogous art directed to the disruption of gene function in target cells (e.g. fungi, plant cells and *C. elegans* in Plaetinck et al and protozoan in Ngo et al). Plaetinck et al specifically teach their invention is directed to

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the disruption of different genes in a target host cell where genomic or cDNA libraries are expressed as dsRNAs in the host cell and gene functions determined. One would have been motivated to combine the teachings of Plaetinck et al with Ngo et al to obtain the expected benefit of being able to identify/characterize a number of different genes in the host cell, as suggested by Plaetinck et al, where the host cell is a protozoan such as suggested by Ngo et al, with a reasonable expectation of success in using the combined teachings to manipulate genes in Trypanosomes (e.g. identification of essential genes for the host cell). Applicants have provided no evidence that the combined teachings would not have a reasonable expectation of success.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is vague and indefinite in that it is unclear the metes and bounds of the term "random DNA". Does the term refer to a DNA synthesized in a purely random manner (e.g. not encoding any natural protein or transcript)? Or does the term mean that the DNA is unknown in the sense that its sequence is not known prior to its insertion into the dsRNA vector of the invention?



***Response to Arguments***

Applicant's arguments filed in the response of 1/20/2004 have been fully considered but they are not persuasive. The response essentially argues the specification makes clear what is encompassed by the term "random DNA" (e.g. page 16, lines 25-31; page 32, lines 3-9). This assertion is not supported by the cited passages as they do not definitively answer the questions raised above.

***Conclusion***

No claims are allowed. Claims 15, 18 & 20 are objected to as being dependent upon a rejected claim, but would be allowable if rewritten in independent form to include all of the limitations of the claims upon which each is currently dependent.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

ggl

  
**GERRY LEFFERS**  
**PRIMARY EXAMINER**